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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/549,312	08/31/2006	Francis Navarro	403504/WEINSTEIN	8215

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EXAMINER	
WACHTEL, EMILY L	

ART UNIT	PAPER NUMBER
3767	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/549,312	NAVARRO ET AL.	
	Examiner	Art Unit	
	EMILY WACHTEL	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 April 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4-15,22 and 23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-2, 4-15, and 22-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. Claims 3 and 16-21 are cancelled. Claims 1-2, 4-15, and 22-23 are pending with claims 1, 2, 4-5, and 7-15 entered as amended. Amendments to the drawings and specification have been entered.

Claim Objections

2. Claims 7 and 23 are objected to because of the following informalities: The claims are unclear as they recite the external pads penetrating the first chamber the recites which substantially closes the second chamber. It is unclear if it is meant that the pads are substantially closing the second chamber or the catheter is being taken to close the second chamber. Appropriate correction is required.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 1-2, 4-5, 7-10, 14-15, and 22-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Landuyt (U.S. Patent 6,387,076 B1) in view of Bierman (U.S. Patent 7,153, 291 B2).

With regard to claim 1, Landuyt teaches a device for fixing a catheter to a patient, comprising a housing (Figure 1- base plate 1 is taken to be functionally equivalent to the

housing), a lid closing the housing (Figure 1 - lid 2, Col. 2 line 27), a base integral to the housing and surrounding the housing, for fixation of the housing to skin of the patient (the base is taken to be the underside/lower portion of base plate 1 which is integral to the housing and contains adhesive for securing the base plate to the patient, Col. 3 lines 6-9 see enclosed reference figure 1), wherein the housing comprises first and second chambers which communicate with each other (Figure 1, chamber 1 is taken to be encompassed by opening 12 and enlarged portion 14, Col. 3 lines 34-46, the second chamber is taken to be encompassed by channel 11 specifically locating region 16, Col. 3 lines 43-44 see enclosed reference figure 1), the first chamber includes an opening for passage of the catheter implanted in the patient (Figure 1 -passage 13 Col. 3 lines 38-40) and the lid includes, on an internal face, two pads which penetrate into the second chamber (Figure 1 -lid 2 comprises gripping means 34 comprising teeth 35 which are taken to be functionally equivalent to the comprised pads, Col. 2 lines 66-67 -Col. 3 lines 1-3). Landuyt does not teach the second chamber accommodates a supporting base of the catheter and includes a reservoir for containing a medicinal product, the reservoir has a first end connected to the catheter and a second end connected to at least one external tube in fluid communication with the catheter, the supporting base of the catheter includes wings respectively extending from opposite lateral faces of the supporting base, and the lid includes, on an internal face, two pads which penetrate into the second chamber and respectively bear on the wings, holding the supporting base of the catheter against a bottom wall of the second chamber, when the lid is closed. However, Bierman teaches a catheter support base with a reservoir (Fig. 1 the reservoir portion taken as 14) with wings (Fig. 1 wings 18) connected to catheter 10 (Fig. 1) and a connection 16 for connecting to an external tube (Fig. 1 Col. 5 lines 34-35). The chamber defined as the second

chamber would be capable of accommodating such a catheter base and an external tube (see enclosed reference figure 1). When closed the pads on the inside surface of the lid would bear down on the base holding it to the bottom of the second chamber. It would have been obvious to a person of ordinary skill in the art at the time the invention was made to use a catheter with a winged support base in the device of Landuyt as taught by Bierman because increasing the surface area of the catheter base along the bottom of the second chamber would provide greater friction between the elements and provide a more stable securement of the catheter.

With regards to claim 2, Landuyt teaches the housing is flat and has a relatively small height with respect to the base (As seen in Figure 1, housing base 1 has a small height with regards to the overall bottom base), the first chamber and the second chamber are approximately co-planar (the chambers as defined in claim 1 can be seen to be approximately co-planer see enclosed reference figure 1), and two pads (Figure 1 -lid 2 comprises gripping means 34 comprising teeth 35 which are taken to be functionally equivalent to the comprised pads, Col. 2 lines 66-67 -Col. 3 lines 1-3), hold the supporting base of the catheter bilaterally with respect to the bottom of the second chamber (the teeth 35 are capable of holding the base of the catheter with respect to the flat bottom, Col. 3 lines 32-36).

With regard to claim 4, Landuyt teaches a catheter retention device substantially as claimed. Landuyt further discloses a wall between the two chambers (see enclosed reference figure) but does not disclose a wall separating the two chambers having oblique lateral faces converging towards the first chamber. However, Bierman teaches that the catheter base support comprises oblique, converging faces (Fig. 5) which are designed to match the shape of the catheter base for better retention. It would have been obvious to a person of ordinary skill in the

art at the time the invention was made to use a wall passage with oblique converging faces in the device of Landuyt because Bierman teaches using retention means which conform to the catheter supporting base and such would provide a more stable securement of the catheter.

With regard to claim 5, Landuyt teaches an adhesive ring around the circumference of the base plate (Col. 3 lines 9-10). This would effectively encompass a membrane on the bottom of the first chamber, as the bottom of the first chamber is taken to be the portion encompassed in the circumference of the lower portion of the base. This also allows for the passage of the base of the catheter.

With regard to claim 7, Landuyt teaches a catheter retention device substantially as claimed. Landuyt further teaches pads which penetrate the second chamber to secure the catheter within the device and also an additional catheter portin extending into the first chamber (Figure 1 -lid 2 comprises gripping means 34 comprising teeth 35 which are taken to be functionally equivalent to the comprised pads, Col. 2 lines 66-67 -Col. 3 lines 1-3). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to further penetrate the first chamber with such pads to provide added securement to the device because Landuyt already teaches using pads for catheter securement and further it is within the skill of one in the art to duplicate parts (In re Harza, 274 F.2d 669, 124 USPQ 378 (CCPA 1960)).

With regard to claim 9, Landuyt teaches the lid and the housing have longitudinal groove to retain a tube (see reference figure 1).

With regard to claim 10, Landuyt teaches the second chamber opens directly

into the first chamber (Figure 1, see chambers as defined in enclosed figure Reference 1) and includes a hollow part having a shape cooperating (chamber 2 has a hollow portion) with an identical hollow part defined between the two pads (two pads are taken to be outer two teeth 35 of figure 1, the hollow shape of the chamber *cooperates* with the space between these two teeth) of the lid to form, when the lid is closed, a recess which matches the base of the catheter for retaining the base in the housing (the catheter base would be retained within the housing).

With regard to claim 14, Landuyt teaches the lid is articulated to the housing for latching (Fig. 1 hinge 3).

With regard to claims 8 and 15, Landuyt teaches the device being stuck to the skin using adhesive (Col. 3 lines 17-18), taken to be functionally equivalent to the colloid.

With regard to claim 22, see the above rejections to claims 1 and 4.

With regard to claim 23, see the above rejections for claims 1 and 7.

5. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over the references set forth in paragraph 4 as applied to claim 5 above, and further in view of Kornerup (U.S. Patent 5,685,859).

With regard to claim 6, Landuyt teaches a catheter retention device substantially as claimed. Landuyt does not teach that the membrane comprises slits extending from an edge which delimits the orifice. However, Kornerup teaches a membrane which more closely surrounds the area in which a tube is inserted into the body and shows a slit (Figure 1 slit 2, Col. 5 line 16) which delimits the device. It would have been obvious to a person of ordinary skill in the art at the time the invention was made to use a membrane with slits in the device of Landuyt

because Kornerup teaches such a membrane and this would provide protection around the area in which the catheter was inserted and that in the case where the membrane would more fully cover the aperture and the area in which the tube is inserted in the that slits would be used because this would allow space to accommodate the insertion of the tube and would allow room for tubes of various sizes.

6. Claims 11 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over the references set forth in paragraph 4 as applied to claim 5 above, and further in view of Bierman (U.S. Patent 6,428,516).

With regard to claims 11 and 12, Landuyt teaches a catheter retention device substantially as claimed. Landuyt does not teach an adhesive including a sheet of flexible material molded with the housing or two holdfasts in the shape of human ears. However, Beirman teaches flexible anchor pad 32 (Figure 1) for securing the retainer to the patient's skin (Col. 7 lines 9-10). This pad is not disclosed to be molded with the housing however, it would have been obvious to a person or ordinary skill in the art to use a one piece construction and make the parts integral (In re Larson, 340 F.2d 965, 968, 144 USPQ 347, 349 (CCPA 1965)). Further, Beirman shows the pad to be in the shape of two human ears so as to provide greater stability and adhesion to the patient's skin. It would have been obvious to a person of ordinary skill in the art at the time the invention was made to attach the device in Landuyt using an adhesive pad molded to the housing the shape of two human ears as taught by Bierman because it would provide greater stability.

7. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over the references set forth in paragraph 6 as applied to claim 12 above, and further in view of Wright et al. (US 2004/0167475 A1).

With regard to claim 13, Landuyt teaches a catheter retention device substantially as claimed. Landuyt does not disclose the housing comprising four support holdfasts in the form of human ears. However, Wright et al. teaches a securement device which has a shape that can be taken to be in the shape of four human ears (Page 4 [0045] Figure 11 base 120). And further, that various shapes can be made as desired. It would have been obvious to a person of ordinary skill in the art at the time the invention was made to use four ear shaped holdfasts as opposed to two in the device of Landuyt because it is within the skill of one in the art to duplicate parts and such has no patentable significance (In re Harza, 274 F.2d 669, 124 USPQ 378 (CCPA 1960)) and further the four holdfasts could provide a support base which better secures the base to the patient as it would provide for increased arrangement possibilities for adhering to the patient's skin, having a greater number of independently movable holdfasts, which could better conform to a variety of locations on the patient.

Response to Arguments

8. Applicant's arguments with respect to the claims, particularly claims 1 and 3, have been considered but are moot in view of the new ground(s) of rejection as necessitated by the amendments to the claims. Generally, regarding the argument that there is not space in the device of Landuyt to accommodate wings, the examiner respectfully disagrees. The chamber as defined by Landuyt has a depth and width which is capable of accommodating a catheter with protruding wings of a sufficient size.

Conclusion

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to EMILY WACHTEL whose telephone number is (571)270-3648. The examiner can normally be reached on Monday through Thursday 7:30 AM to 5:00 PM (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Emily Wachtel/
Examiner, Art Unit 3767
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